UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

LOUISIANA WHOLESALE DRUG COMPANY, INC., *et al.*,	:	
Plaintiffs,	:	
v.	:	Civil Action No. 04-2235 (JR)
BIOVAIL CORPORATION, *et al.*,	:	
Defendants.	:	

MEMORANDUM

Three related antitrust actions have been filed against Biovail Corporation in this court. All three are by purchasers of Biovail's brand-name drug Tiazac. All three demand damages for antitrust injuries that the plaintiffs attribute to Biovail's unlawful (but successful) attempts to keep cheaper generic versions of Tiazac off the market. The first two of these cases, Twin Cities Bakery Workers Health & Welfare Fund v. Biovail Corp., No. 01-2197, and Meijer, Inc. v. Biovail Corp., No. 03-2075, were consolidated. On March 31, 2005, I granted summary judgment in the consolidated cases in favor of Biovail, No. 01-2197 [66, 67], 2005 U.S. Dist. LEXIS 5570, upon a finding that the plaintiffs could not prove that Biovail's unlawful acts caused them injury. The plaintiffs' appeal from that judgment is pending before the Court of Appeals, which has stayed its hand pending my decision on Biovail's motion for summary judgment in this, the third of the three cases.

The background facts of the instant case – Biovail's marketing of Tiazac after the approval of its NDA in 1995, its acquisition of patents and its invocation of the Hatch-Waxman Act to delay approval of the generic drug developed by Andrx Pharmaceuticals, Inc., the difficulties Andrx encountered in bringing its generic drug to market – are identical to those of the earlier consolidated cases. Those facts are set forth in the Twin Cities decision and will not be repeated here.[1] In one important respect, however, this case is distinguishable from the other two: this plaintiff has identified a new and quite different factual basis for the antitrust injury it claims. In Twin Cities and Meijer, the alleged antitrust injury was loss of the opportunity to purchase the cheaper Andrx generic product that would have been on the market except for Biovail's unlawful acts. Louisiana Wholesale Drug Company makes the same allegation, but it also alleges that, whether or not Andrx would have or could have brought its generic product to market, Biovail itself was preparing to market a generic version of its own drug (a "branded generic") and, had it not succeeded in blocking the Andrx ANDA for a second time in 2001, would have done so.

The present summary judgment motions revisit the questions that were decided in Twin Cities. They also present

[1] The memorandum opinion in Twin Cities contained a factual error that is identified, corrected, and discussed infra.

two new questions: (I) whether Louisiana Wholesale's allegation of loss from Biovail's refusal to market a generic version of its own brand-name drug states a claim under the Clayton Act, and (ii) if so, whether the claim as to Biovail's own generic product (which first appeared in an amended complaint filed two months after the entry of summary judgment in Twin Cities) is time barred.

Factual allegations by Louisiana Wholesale that were not pleaded in *Twin Cities*

In its amended complaint, Louisiana Wholesale alleges that Biovail and its distributor and co-conspirator Forest Laboratories anticipated that Andrx would prevail in the Federal Circuit patent appeal that was then the only barrier to FDA approval of Andrx's ANDA (see Twin Cities, [66] at 3-4) and planned to beat Andrx to market with a generic form of Tiazac that Biovail itself would produce.[2]

By March 2000, Biovail and Forest had determined the inventory level they would need in order to supply 100 percent of the anticipated generic demand for four months. By August 2000, Biovail and Forest had agreed that, with some pricing discipline, both would benefit from bringing a Biovail generic to market ahead of Andrx. In October 2000, Biovail's chairman Eugene

[2] The manufacturer of an FDA-approved drug needs no further approval to manufacture and distribute the drug under a generic label. See 21 U.S.C. § 355.

Melnyk confirmed to investment analysts that Biovail was planning to "pre-emptively" launch its own generic, leveraging Tiazac sales into generic purchase agreements with large Tiazac purchasers. The agreements would provide the purchasers with financial incentives that would make it too costly to switch to Andrx's generic when it entered the market. By the end of October 2000, only a few minor administrative tasks remained before the preemptive generic launch could occur. By mid-November, bottles and caps had been completed, and many lots of the defendants' generic Tiazac capsule had been produced. The stock was ready in mid-December 2000, waiting for the anticipated Federal Circuit decision in the '791 patent case that would trigger Biovail's planned launch of its own generic. [22] at 17-22; [36] at 11-13.

Biovail and Forest, however, never launched the branded generic. They abandoned their plan when Biovail obtained and listed the '463 patent, starting the Hatch-Waxman process all over again and making it unnecessary for Biovail to compete against itself.

Analysis

1. Plaintiff has neither added to the proof of causation found insufficient in *Twin Cities* nor demonstrated that the judgment in *Twin Cities* was erroneous.

In its opposition to the present motions for summary judgment, Louisiana Wholesale submits, just as the Twin Cities plaintiffs did, that, but for Biovail's improper Orange Book listing of the '463 patent, Andrx would have obtained FDA approval for its generic product on or about February 13, 2001, and that it (Louisiana Wholesale) would have been able to buy Tatzia shortly thereafter. Plaintiff does not augment the factual showing of causation that was made in the Twin Cities cases. Instead, to avoid the application of *stare decisis*,[3] plaintiff essentially seeks reconsideration of Twin Cities, pointing to a factual error in that decision and to what it asserts are the findings of other courts.

The factual error was a statement in Twin Cities that Andrx moved forward as best it could with Tatzia during the '791 and '463 litigation, especially during the period of February 13, 2001 to April 5, 2001, "during which no stay clouded its

[3] "A decision of a federal district judge is not binding precedent in either a different judicial district, the same judicial district, or even upon the same judge in a different case." 18 Moore's Federal Practice 3D § 134.02[1][d]. However, "[a] court should give considerable weight to its own previous decisions unless and until they have been overruled or undermined by the decision of a higher court or a statutory overruling." Id. at § 134.02[1][a].

application." In fact, there was a stay in place with respect to Andrx's ANDA, between February 13, 2001 and April 5, 2001. The FDA could not lawfully have approved Andrx's ANDA during most of that period because of the 45-day stay that took effect after Andrx's second Paragraph IV certification. In the submission of Louisiana Wholesale, this factual error significantly undercuts the validity of the Twin Cities outcome.

The error is acknowledged, but plaintiff has greatly overstated its significance. Even while the statutory stay was in effect, the FDA could have granted tentative approval of Andrx's amended ANDA, as it did with Andrx's original ANDA in September 2000, but it did not grant tentative approval until May 14, 2001 – only days before Andrx became aware of the massive dissolution failures in its January 2001 lot. The Twin Cities decision turned on the "number of uncertain links in a causal claim." Plaintiff has pointed out that one of the links is stronger than I had thought, but the overall proof of causation remains too weak as a matter of law to support plaintiff's claim.

The asserted findings of other courts were statements made by the United States District Court for the Southern District of Florida and by the United States Court of Appeals for the Federal Circuit in litigation between Andrx and Biovail over the '463 patent and the Hatch-Waxman Act stay. Plaintiff asserts that both courts made findings that, but for the '463 litigation,

the FDA would have approved Andrx's ANDA shortly after the termination of the '791 litigation, and that those findings are owed at least deference, if not preclusive effect. [55] at 29. After careful review of the materials plaintiff has submitted, [55] at 30-31, I have concluded that the "findings" – if they were findings at all – have no weight in this antitrust litigation. In neither the Florida court nor the Federal Circuit was the question of whether the FDA would have approved the Andrx ANDA in February 2001 at issue. The question before the Florida court was whether the '463 patent should be delisted or the Hatch-Waxman stay shortened. The court's focus was on patent-related legal barriers to the approval of Andrx's application, not on the progress of the FDA's regulatory and scientific review of that application. When the Florida court said that FDA would have approved Andrx's ANDA on or about February 13, 2001, Andrx Pharms., Inc. v. Biovail Corp., 175 F. Supp. 2d 1362, 1365 (S.D. Fl. 2001),[4] it was stating an assumption, not making a finding of disputed fact. The Federal Circuit's statement that the FDA would have approved the ANDA on or around February 13, 2001, was also an assumption, one clearly based on the tentative approval issued by the FDA in September 2000 and on no other information.

[4] "On February 13, 2001 ... the Federal Circuit upheld this Court's decision that Andrx's generic drug did not infringe the '791 patent... Thus, the FDA would have approved Andrx's drug on or about February 14, 2001, if not for the actions regarding the '463 patent at issue in this case." Id.

Andrx Pharms., Inc. v. Biovail Corp., 276 F.3d 1368, 1372 (Fed. Cir. 2002).[5] Neither court appears to have had before it evidence of the activity with respect to Andrx's ANDA that occurred after the September 2000 tentative approval. In both cases, plaintiffs are conflating statements made by other courts that Tatzia would be eligible for final FDA approval upon the lifting of related stays,[6] with an actual adjudication on the merits that the FDA would approve Taztia when those stays were lifted. The two are not the same, and the first cannot be used to prove the second.

Plaintiff has not demonstrated that it can establish the requisite causal link for its claim of injury from Andrx's inability to market Tatzia. On that claim, then, the result in this case is the same as in Twin Cities.

2. Plaintiff's new claim based on Biovail's abandonment of plans to market its own generic product does allege antitrust injury

Two months after the Twin Cities plaintiffs' attempts to link Biovail's actions to their alleged injuries were found

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[5] "Thus, but for the present dispute, the FDA would have approved Andrx's ANDA on or shortly after February 13, 2001. n2 However, the present dispute intervened.

* * * * *

n2 In September 2000 Andrx had received tentative approval of its ANDA from the FDA, pending expiration of the statutory stay period." Id.

[6] The statement plaintiffs cite from the FDA, [55] at 30, is only that Andrx's ANDA "would have been eligible for approval on February 13, 2001" (emphasis added). [55] at Exh. 7, 7.

insufficient, Louisiana Wholesale amended its complaint to add the new allegation that Biovail had planned to market its own generic but scrapped that plan after it acquired and listed the '463 patent, [55] at 43; that Louisiana Wholesale was accordingly forced to pay supra-competitive prices for Tiazac; and that it is entitled to treble damages under § 4 of the Clayton Act.

To recover treble damages under § 4, a plaintiff must prove "an injury of the type antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful," Brunswick Corp. v. Pueblo Bow-o-Mat, Inc., 429 U.S. 477 (1977). These defendants submit that Louisiana Wholesale's new claim fails both parts of that test – that inability to purchase a branded generic product is neither the type of injury the antitrust laws were designed to prevent nor an injury that flows directly from the anti-competitive consequences of the '463 patent listing. [32] at 27. The argument, in other words, is that the prices plaintiff paid for Tiazac flowed from a perfectly lawful decision by Biovail not to market a lower-priced branded generic version of its own drug.

"Otherwise legal" actions can be actionable under the antitrust laws and confer standing under § 4 of the Clayton Act if they are part of an anti-competitive scheme. "It is not of importance whether the means used to accomplish the unlawful objective are in themselves lawful or unlawful." American

Tobacco Co. V. U.S., 328 U.S. 781, 809 (1946). In that case, the tobacco company parties dominated the market for domestic cigarettes and engaged in collusive practices to ensure that they would all buy tobacco at the same price and in the same markets. Id. at 792-794. In discussing the steps taken by the companies, the Court stated:

> It is not the form of the combination or the particular means used but the result to be achieved that the statute condemns. . . . Acts done to give effect to the conspiracy may be in themselves wholly innocent acts. Yet, if they are part of the sum of the acts which are relied upon to effectuate the conspiracy which the statute forbids, they come within its prohibition.

Id. at 809.

In litigation in this Circuit involving another drug, Andrx v. Biovail, 256 F.3d 799 (D.C. Cir. 2001), Biovail was the antitrust plaintiff, alleging that it had suffered antitrust injury when Andrx accepted a multi-million dollar payment from HMRI, a brand-name drug manufacturer, agreeing in exchange not to market a generic version of HMRI's Cardizem CD. The effect of that agreement was completely to preclude Biovail from marketing its own generic for Cardizem, because Andrx's was the "first-filed" generic, entitled under applicable law to 180 days of marketing exclusivity. Because the 180 days would not begin to run until Andrx began marketing its generic, and because Andrx had agreed not to market its generic at all, Biovail's generic was blocked.

The D.C. Circuit accepted Biovail's argument that these allegations described antitrust injury, notwithstanding Andrx's position that Andrx "could have lawfully excluded Biovail from the Cardizem CD market by deciding, on its own, to delay marketing of its generic version of Cardizem CD." 256 F.3d at 813. The court found:

> If Biovail's allegations are correct, the Andrx-HMRI Agreement neither enhanced competition nor benefitted consumers: if anything it accomplished just the opposite by preserving HMRI's monopoly. Moreover, Biovail alleged that its exclusion from the market occurred not only by reason of the unlawful agreement, but also by reason of that which made the Agreement unlawful, that is, the illegal restraint of trade. . . . As Biovail has pleaded the facts, HMRI and Andrx combined to achieve an unlawful objective. . . . Accordingly, we conclude that Biovail can allege an antitrust injury, that is, one the antitrust laws were designed to prevent and that flows from that which makes the defendant's conduct unlawful.

Id. at 815-16.

Louisiana Wholesale's allegations of antitrust injury fit within that rule. If the allegations are true, Biovail's decision not to market a branded generic was unlawful because it was part of a scheme to maintain supra-competitive prices by any effective means, including the unlawful listing of the '463 patent. Illegally-maintained supra-competitive pricing is the kind of injury the antitrust laws were designed to prevent, and injuries caused by such activity flowed from an illegal scheme.

3. Because plaintiff's newly alleged injury does not relate back to the original complaint, it is time-barred

Louisiana Wholesale's claim of antitrust injury flowing from Biovail's decision not to market its own generic was first stated in its amended complaint, filed on June 1, 2005. Defendants' motion for summary judgment interposes a statute of limitations defense, to which plaintiff makes two responses. First, relying on Hanover Shoe v. United Shoe Mach. Corp., 392 U.S. 481, 502 n.15 (1968), it asserts that a new claim has accrued each time it has paid a supra-competitive price for Tiazac, so that its claim was timely filed at least to the extent that it paid artificially-inflated prices beyond June 1, 2001. "So long as a monopolist continues to use the power it has gained illicitly to overcharge its customers, it has no claim on the repose that a statute of limitations is supposed to provide." Berkey Photo, Inc. V. Eastman Kodak, 603 F.2d 263, 295 (2d Cir. 1979).

Assuming the truth of Louisiana Wholesale's claim that Biovail abandoned its plan to bring out a branded generic because it had acquired and unlawfully listed the '463 patent, however, that unlawful behavior could not have been the but-for cause of any loss from supra-competitive pricing after May 18, 2001 – the date on which Andrx became aware of Tatzia's significant manufacturing problems. After that date, Biovail no longer faced

the threat of competition by an Andrx generic product and was under no legal obligation to carry through with its plan to "compete against itself." It might be argued that plaintiff continued to pay supra-competitive prices for Tiazac after May 18, 2001, because, if Biovail had introduced its generic product as planned on or about February 13, 2001, unsold lots would still be on the market three months later when Andrx's production problems became apparent; or because Biovail might have continued to sell its generic product, either in ignorance of Andrx's problems or reckoning that Andrx would soon solve them; or simply because by this time Biovail would have established a course of dealing with purchasers of its generic drug that would have been costly or difficult to interrupt. Because Biovail never did actually market its product, however, and because Andrx neither sold nor attempted to sell its generic drug from May 18, 2001, until it settled with Biovail on July 12, 2002, such theories of damages would have nothing but pure speculation for support and could not stand.

Louisiana Wholesale's second response to the statute of limitations defense is that, even if it cannot prove that it paid supra-competitive prices for Tiazac after May 18, 2001, its claim for damages between February 13 and May 18 relates back to its original complaint, filed on December 28, 2004, and is thus timely. [37] at 40. An amended complaint "relates back" only

when "the claim or defense asserted in the amended pleading arose out of the conduct, transaction or occurrence set forth in the original pleading." Fed. R. Civ. P. 15(c)(2). The cases impose two distinct criteria. First, the claim must arise from the same set of operative facts set out in the original complaint, and second, the opposing party must have been put on notice by the original complaint of the claim alleged in the amended pleading. "[B]oth elements – same conduct and adequate notice – must be satisfied before relation back of new claims is permitted." See Const. Interior Sys., Inc. v. Donohoe Cos., 813 F. Supp. 29, 37 (D.D.C. 1992). An amended complaint that "attempts to introduce a new legal theory based on facts different from those underlying the timely claims" will not relate back. United States v. Hicks, 283 F.3d 380, 388 (D.C. Cir. 2002).

In defendants' submission, Louisiana Wholesale's new claim based on Biovail's decision not to produce and market a branded generic cannot relate back because (I) it introduces a new legal theory of causation that is based on a new set of operative facts that were not alleged in the original complaint, and (ii) the original complaint did not put defendants on notice that they would have to defend against claims arising out of a decision not to compete against themselves. [32] at 17.

Louisiana Wholesale's new claim is of course factually related to its original claim of injury based on Biovail's

wrongful acts to keep the Andrx generic off the market, but claims must be more than factually related to "arise out of" the same conduct. In Construction Interior Sys. v. Donohoe Cos., supra, the plaintiff, a subcontractor, brought claims against the contractor on a remodeling project for breach of contract and unjust enrichment. After the statute of limitations had run, plaintiff sought leave to file an amended complaint that added a claim of tortious interference with contractual rights on the same construction job. Leave to file was denied, because the new claim, "while factually connected, [did] not 'arise' out of the conduct alleged in the original complaint." Id. at 36, citing Monks v. Marlinga, 732 F. Supp. 749, 754 (E.D. Mich. 1990)(slander claim concerning conduct while employed did not relate back to wrongful discharge claim based on same alleged conduct). As the Court of Appeals has more recently explained, Congress did not intend Rule 15(c) to be so broad as to permit relation back where "an amended pleading add[s] an entirely new claim based on a different set of facts." Hicks, 283 F.3d at 388-89, quoting Dean v. United States, 278 F. 3d 1218, 1221 (11th Cir. 2002). In Dean, involving a plaintiff who suffered brain damage during surgery, the original complaint was for failure to inform the plaintiff of an alternative surgery. The amended complaint added a negligence claim. The court held that even though the new claim arose from the same injury as the original

claim, it would not "relate back" because it involved "separate and distinct conduct." See Moore v. Baker, 989 F.2d 1129, 1132 (11th Cir. 1993).

In this case, Louisiana Wholesale's new theory of antitrust injury relies upon allegations of fact that are entirely new. The original complaint does not even hint that Biovail ever planned to produce a branded generic or that it abandoned that plan – facts without which plaintiffs' new claim of antitrust injury could not stand.[7]

The significant difference between the facts and theories alleged in the original and amended complaints is also dispositive of the second criterion of the relation-back test: notice to defendants of the claims against which they would have to defend. The Moore court called notice the "critical issue in Rule 15(c) determinations." 989 F.2d at 1131. In Construction Interior, the court observed that, given the plaintiff's early knowledge of the facts underlying its tortious interference claim, the plaintiff's failure to include the claim in prior timely complaints "could easily, and reasonably, be interpreted as implicit notice that it would not be pursuing the tortious interference claim." 813 F. Supp at 37. Here, the defendants

[7] The plaintiffs in Twin Cities and Meijer did not advance this claim, nor do the records of those consolidated cases contain any mention Biovail's plan to bring its own generic to market.

made public statements as early as 2000 regarding their plans to launch a branded generic product as soon as Tatzia was no longer legally barred from competing with Tiazac. Plaintiffs could have ascertained the basic facts underpinning their Biovail-generic claim and included those facts in their original complaint, which would have allowed them to flesh out the claim, as needed, in the amended complaint. Instead, there is simply no indication in the original complaint that plaintiffs intended to pursue this line of argument.

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For the foregoing reasons, the defendants' motions for summary judgment [32, 33] will be granted. An appropriate order accompanies this memorandum.

JAMES ROBERTSON
United States District Judge